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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,098	03/03/2000	Leland Shapiro	114232.107	5420

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,098	SHAPIRO, LELAND	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *1-39,41 and 43-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,42 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 20 (filed 6/5/02), claims 40-42 have been amended, and claim 46 added. Claims 1-46 are pending. Claims 1-39, 43-45 remain withdrawn from consideration; in addition, claim 41 is withdrawn because it does not encompass the elected specie. Claims 40, 42, 46 are examined in this Office action.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated previously, the claims encompass a method of treating HIV infections in humans. However, applicant's *in vitro* experiments do not enable this extrapolation. As stated in *Ex parte Forman* (230 USPQ 546, 1986) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence

of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. As stated in Mangos (*Texas Medicine*, **86**, 40, 1990):

> "In spite of ... [therapy against HIV and opportunistic infections], the universal outcome of HIV infection / AIDS is the death of the patients" (see, e.g., abstract).

As disclosed in Binquet (*AIDS* **12**, 2313, 1998) a total of 556 patients were treated with HIV protease inhibitors for a period of 230 days, and that despite being treated with with HIV protease inhibitors for more than seven months, 24 of the patients had died. Both of these references teach that death occurs in spite of administration of HIV protease inhibitors. If death is the result of a treatment, one cannot say that success (in the treatment) is predictable.

If sucess is not predictable, it must be "unpredictable". Given that treatment of AIDS is "unpredictable", it follows therefrom that "undue experimentation" would be required to determine which, if any, of the claimed compounds can be used to treat patients afflicted with AIDS. [*Ex parte Balzarini,* 21 USPQ2d 1892)]. Thus, extrapolation from *in vitro* inhibition of viral replication in a petri dish to a therapy in humans is unpredictable.

In response to the foregoing, applicants have cited *In re Krimmel.* In *Krimmel*, the claims at issue were drawn to compounds *per se*, i.e., there were no method claims (at least none mentioned in the USPQ citation). Second, the applicant provided both *in vitro* and *in vivo* data (using rabbits). Third, the asserted uses of the claimed compounds in *Krimmel* were (a) inhibition of bacterial growth, and (b) inhibition of inflammation. The

facts of that case are different in all three respects from those of the instant case. In the instant case, the claims at issue are all drawn to methods, not to compounds (*per se*). Second, no *in vivo* data has been supplied (in the instant case) , and third, there were, at the time of the prosecution of the *Krimmel* case, suitable animal models for the asserted therapies. Applicants have not identified any suitable animal models for AIDS, and have provided no data from such animal models. Thus, Krimmel is not controlling in the instant case. [While applicants have cited neither *In re Brana* nor *Cross v. Iizuka*, it is noted preemptively that in both of those cases the only claims under consideration by the Court were drawn to compounds *per se*. No method claims were at issue].

It is suggested that, in claim 40, the phrase "therapeutically effective" be deleted.

*

Claims 40, 42, 46 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Each of claims 40 and 46 recite that a compound can exhibit an activity which is somehow "like" that of α1-antitrypsin. This renders the claims indefinite as to the manner in which and the extent to which, the compound must resemble α1-antitrypsin.

- Claim 42 recites various trademark names. These may be used, but only if accompanied by the full name of the compounds that are represented. (The same issue applies in the case of claim 41, though withdrawn from consideration).

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 40 is rejected under 35 U.S.C. §103 as being unpatentable over Lezdey (USP 5,532,215).

As indicated previously, Lezdey discloses (col 6, line 31) that serine protease inhibitors can inhibit HIV replication. The reference also discloses one or more serine protease inhibitors that are asserted to have this property. The reference also does not teach combining a serine protease inhibitor with an HIV protease inhibitor.

In response to this ground of rejection, applicants have pointed to page 9, line 23+ where it is asserted that Vollenweider F (*Biochemical Journal* **314** (Pt 2) 521-32, 1996) and Anderson (*J. Biol. Chem.* **268**, 24887, 1996) both disclose that α1-antitrypsin fails to inhibit HIV replication. This may be the assertion in the specification, but it is not apparent where in the text of either article such failure is disclosed. In further arguing that Vollenweider

and Anderson provide evidence that α1-antitrypsin does not inhibit HIV replication, applicants are requested to identify the passage in the text of the articles.

At the present time, there is no evidence that the disclosure of Lezdey is flawed. The rejection is maintained.

*

Claims 40, 42 and 46 are rejected under 35 U.S.C. §103 as being unpatentable over Eisenberg (U.S.P. 6,017,880).

As indicated previously, Eisenberg discloses (col 2, line 7+; col 2, line 20+) that serine leukocyte protease inhibitor can inhibit HIV replication. In response, applicants have amended claim 40 to exclude "serine leukocyte protease inhibitor" (SLPI) . First, claim 46 does not exclude SLPI, and so the rejection is appropriately imposed against claim 46. Second, the amendment to claim 40 is not effective to overcome this ground of rejection. The reason is that Eisenberg discloses various analogs and mutants of SLPI. For example, at col 4, line 44, the derivative "CLPI" is disclosed. Thus, the amendment to claim 40 is regarded as excluding one specie, but Eisenberg discloses a genus. The rejection is maintained.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600